SECTION 6

POLLUTANTS SELECTED FOR REGULATION

6.1 Introduction

EPA has reviewed wastewater characterization data available from the Detailed Questionnaire responses and EPA sampling results to determine the presence or absence of conventional, nonconventional, and priority pollutants in pharmaceutical manufacturing process wastewaters. Using this information, EPA determined pollutants likely to be present and pollutants identified as being discharged by the pharmaceutical manufacturing industry. This presents the results of that study and identifies the pollutants and pollutant parameters the Agency is regulating under BPT, BCT, and BAT effluent limitations guidelines and NSPS, PSNS, and PSES, as appropriate.

EPA is authorized to regulate conventional and priority pollutants under Sections 304(a)(4) and 301(b)(2)(C) of the Clean Water Act (CWA), respectively. The list of toxic pollutants from 307 of the CWA has been expanded to include 126 priority pollutants identified in the Settlement Agreement of NRDC vs. Train.(1) In addition, the Agency may also regulate other nonconventional pollutants, taking into account factors such as treatable amounts, toxicity, analytical methods, frequency of occurrence, use of indicator pollutants, and the pass through of pollutants at Publicly Owned Treatment Works (POTWs).

The following information is discussed in these sections:

- 6.2 discusses the pollutants considered for regulation;
- 6.3 discusses the pollutants discharged by the pharmaceutical manufacturing industry;
- 6.4 presents the pollutant selection evaluation criteria;
- 6.5 discusses the conventional pollutants considered and selected for regulation;

- 6.6 discusses the priority pollutants considered and selected for regulation; and
- 6.7 discusses the nonconventional pollutants considered and selected for regulation.

6.2 Pollutants Considered for Regulation

Prior to 1986, the Agency's regulatory focus for the pharmaceutical manufacturing industry was on five conventional pollutants and 126 priority pollutants. In 1986, the Agency expanded the analysis of the industry's wastewater to determine the presence and levels of the Industrial Technology Division (ITD) List of Analytes, which was derived from the ITD List of Lists, as described in 3.2.3. The List of Analytes was revised in 1990 to include 458 analytes. EPA conducted a study to determine which of these 458 analytes could potentially be discharged in pharmaceutical manufacturing wastewaters in significant amounts. The study included a review of the prior pharmaceutical rulemaking and available literature, an evaluation of EPA and industry sampling data obtained prior to 1986, data reported in the Detailed Questionnaire, data submitted by the industry in connection with the Detailed Questionnaire, data obtained from EPA sampling at pharmaceutical manufacturing facilities, and industry-supplied corrections to the Detailed Questionnaire data.(2) These data-collection efforts were discussed in greater detail in 3.

The Agency's evaluation of the industry resulted in a list of 146 conventional, nonconventional, and priority pollutants and pollutant parameters which may be present in the industry's wastewater (see Table 6-1). The pollutants and pollutant parameters identified as likely to be present are predominantly volatile and semivolatile organic compounds. Other parameters which may be present are ammonia and cyanide. Although metals are used in some pharmaceutical manufacturing processes, they were not discharged at concentrations high enough to warrant control on an industry-wide basis. 3 describes in detail the criteria used by the Agency to identify those pollutants which may be present in the industry's wastewater.

6.3 Pollutants Discharged by the Pharmaceutical Industry

EPA requested discharge information on 143 of the 146 pollutants and pollutant parameters which may be present in the industry's wastewater in the Detailed Questionnaire sent to pharmaceutical manufacturing facilities in Subcategories A, B, C, and D. Discharge information was not collected on pH, oil and grease, and fecal coliform. Regulations governing control of pH in pharmaceutical manufacturing wastewater are not being revised. Oil and grease and fecal coliform are not significant pollutants in this industry. The Agency used the responses to this questionnaire to identify which of the pollutants likely to be present were being discharged by the industry.

Responses to 3-1 of the Detailed Questionnaire indicated that the following 17 priority pollutants and 36 nonconventional pollutants identified as potentially present in the industry's wastewater were not reported as discharged in pharmaceutical manufacturing wastewaters in 1990:

Priority Pollutants Not Reported as Discharged	
Acrolein	1,2-Dichloropropane
Acrylonitrile	Hexachlorocyclapentadiene
Benzidine	Hexachloroethane
Bromoform	Nitrobenzene
Bromomethane	2-Nitrophenol
Chloroethane	4-Nitrophenol
p-Dichlorobenzene	Trichloroethylene
1,1-Dichloroethane	Vinyl Chloride
1,1-Dichloroethene	
Nonconventional Pollutants Not Reported as Discharged	
Acetophenone	N-Dipropylamine
4-Aminobiphenyl	Epichlorohydrin
Benzotrichloride	Ethyl Cyanide
Benzyl Bromide	2-Hexanone
Biphenyl	Iodoethane
2-Bromo-Propanoylbromide	2-Methoxyaniline
N-Butylamine	Methyl Methacrylate

Nonconventional Pollutants Not Reported as Discharged	
sec-Butyl Alcohol	N-Nitrosomorpholine
Catechol	n-Pentane
2-Chloroacetophenone	B-Propiolactone
3-Chloro-4-Fluoroaniline	1,3-Propane Sulfone
Chloromethyl Methyl Ether	Propionaldehyde
Cresol (Mixed)	1,2-Propyleneimine
Cumene	Styrene
1,2-Dibromoethane	Tetrachloroethene
Diethyl Carbonate	1,2-trans-Dichloroethene
Diethyl-ortho Formate	2,4,5-Trichlorophenol
1,1-Dimethylhydrazine	Vinyl Acetate

These 17 priority and 36 nonconventional pollutants were excluded from consideration for regulation, leaving 90 conventional, priority, and nonconventional pollutants and pollutant parameters reported as discharged as potential candidates for regulation.

6.4 Pollutant Selection Evaluation Criteria

Having identified those pollutants of concern being discharged by the pharmaceutical manufacturing industry, the Agency next considered which of those pollutants should be controlled. The NRDC Consent Decree included a defined set of criteria for selecting pollutant parameters to be regulated.(1) While no longer bound by the conditions of the NRDC Consent Decree, the Agency used a similar screening protocol for selecting pollutants and pollutant parameters for this regulation. Pollutants were excluded from consideration for regulation based on the following criteria:

- The pollutant is discharged in relatively small amounts (<3,000 lbs per year) and is neither causing nor likely to cause toxic effects;
- The pollutant is not effectively treated by the use of treatment technologies selected under BAT or PSES;
- The pollutant is reported or detected in the effluent from a small number of sources, and is uniquely related to these sources;

- The pollutant cannot be analyzed by EPA-approved or other state-of-the-art established methods;

- Additionally, pollutants considered for regulation that were found to have minimal load reduction through implementation of BAT and PSES for A/C and B/D subcategories were not selected for regulation.

The Agency considered the available pollutant data (from existing rulemakings and available literature, evaluation of existing data, data obtained from the Detailed Questionnaire, data submitted by industry, and data obtained from EPA sampling at pharmaceutical manufacturing facilities) against the selection criteria cited above. Sections 6.4.1 through 6.4.4 summarize EPA's assessment of these evaluation criteria for 86 priority and nonconventional pollutants discharged by the pharmaceutical manufacturing industry. The other 4 of the 90 constituents identified as being discharged by the pharmaceutical manufacturing industry (cyanide, COD, and the conventional pollutants BOD_5 and TSS) are considered in Sections 6.5, 6.6, and 6.7. Table 6-2 summarizes the information obtained for each of the 86 priority and nonconventional pollutants identified as discharged by the pharmaceutical manufacturing industry.

6.4.1 Quantity Discharged

The quantity of each of the 86 priority and nonconventional pollutants discharged by the pharmaceutical manufacturing industry in 1990 ranged from 1 lb/yr to 13,200,000 lbs/yr. Table 6-2 lists these pollutants by total quantity discharged in process wastewaters. Table 6-2 also presents the percentage of total organic loading contributed by each constituent. Those pollutants discharged at 98,400 lbs/yr and above represent approximately 99% of the total organic loading discharged in 1990.

6.4.2 Treatability

Pollutant treatability was evaluated for the two main technologies utilized by the pharmaceutical manufacturing industry, biological treatment and steam stripping. Steam stripping treatability was evaluated using a pollutant's Henry's Law Constant. Biological treatability was evaluated by considering available biotreatability rate constants (Kmax) and/or the ratio of BOD to theoretical

oxygen demand (ThOD) (4,5). Henry's Law and Kmax constants, as well as the BOD/ThOD ratio, are general indicators of treatability. All pollutants were found to be treatable by either steam stripping or biological treatment.

6.4.3 Number of Facilities Discharging Pollutants

Table 6-2 lists the number of facilities reporting discharges of each pollutant and the number of facilities reporting a pollutant in their raw 1990 loads.

Some pollutants were found to be discharged by only one facility in 1990 and were unique to that one facility. Other pollutants such as benzene were reported as discharged by only one facility in 1990 but were present at more than one facility. Due to the variable nature of this industry, EPA has not excluded pollutants for regulation that may be present at more than one facility and are discharged in significant amounts. Benzene is a good case in point, since even though only one facility identified it as discharged in 1990 it was found to be present in 10 of the samples taken by EPA in August 1996 at the Barceloneta Regional Wastewater Treatment Plant which is a POTW that receives predominately pharmaceutical wastewaters along with domestic and food-processing wastewaters.

6.4.4 Load Removed

After identifying pollutants to be considered, EPA analyzed the load reduction of these pollutants. 9 provides specific information on calculation of pollutant loads and pollutant load reduction. Table 6-5 presents the pollutant load reductions expected through implementation of BAT and PSES regulations for A/C and B/D facilities.

6.5 Conventional Pollutants Considered and Selected for Regulation

Conventional pollutants include BOD_5, TSS, fecal coliform, pH, and oil and grease. These pollutants are general indicators of water quality rather than specific compounds. BOD_5, TSS,

and pH are regulated by current BPT limitations; with this final rule, EPA is retaining the existing BPT limitations for BOD_5, TSS, and pH.

Oil and grease and fecal coliform were not considered for regulation in the pharmaceutical manufacturing industry. Although oil and grease may appear in some plant process wastewater, it is not sufficiently widespread or discharged at concentrations high enough to justify regulation on an industry-wide basis. Fecal coliform is related to sanitary discharges and not discharges from specific pharmaceutical manufacturing process wastewaters and, therefore, was also not considered for regulation.

6.6 Priority Pollutants Considered and Selected for Regulation

6.6.1 Priority Pollutants Considered for Regulation

Thirty-two priority pollutants were considered for regulation in the pharmaceutical manufacturing industry (see Table 6-1). Seventeen of these were not reported as discharged in pharmaceutical manufacturing wastewaters based on the Detailed Questionnaire. Of the fifteen remaining, six were not selected for regulation because they were discharged on an industry-wide basis at less than 3,000 lbs/yr. A review of their treatability, treatment performance data availability, number of facilities discharging, analytical methods, and load discharged does not support the need for regulation. Table 6-3 lists these six priority pollutants and the reasons for their exclusion from the list of pollutants to regulate. The remaining 9 were identified as candidates for regulation:

Benzene
Chlorobenzene
Chloroform
Cyanide
o-Dichlorobenzene (1,2-Dichlorobenzene)
1,2-Dichloroethane
Methylene chloride
Phenol
Toluene

6.6.2 Priority Pollutants Selected for Regulation

EPA analyzed the load reduction of these nine priority pollutants expected through implementation of BAT and PSES for A/C and B/D subcategories. 9 provides specific information on calculation of pollutant loads and pollutant load reduction. Table 6-5 presents the expected pollutant load reductions. The Agency has previously regulated cyanide in the pharmaceutical manufacturing industry under BPT and is not revising those regulations for Subcategories A and C. The previous cyanide regulation is being withdrawn for Subcategories B and D, because EPA has determined that cyanide is neither used nor generated by facilities with these subcategory operations.

For A/C facilities, the remaining eight priority pollutants have been selected for regulation:

Benzene
Chlorobenzene
Chloroform
o-Dichlorobenzene (1,2-Dichlorobenzene)
1,2-Dichloroethane
Methylene chloride
Phenol
Toluene

For B/D facilities, seven of the remaining eight priority pollutants were found to have minimal load reduction under the selected regulatory options (in all cases less than 75 lbs/year), and therefore have not been selected for regulation.

Benzene
Chlorobenzene
Chloroform
o-Dichlorobenzene (1,2-Dichlorobenzene)
1,2-Dichloroethane
Phenol
Toluene

The remaining priority pollutant selected for regulation at B/D facilities is methylene chloride.

6.7 Nonconventional Pollutants Selected for Regulation

6.7.1 Nonconventional Pollutants Considered for Regulation

One hundred and nine nonconventional pollutants were considered for regulation in the pharmaceutical manufacturing industry (see Table 6-1). Thirty-six of these were not reported as discharged in pharmaceutical manufacturing wastewaters from process wastewaters based on the Detailed Questionnaire. Of the remaining 73 nonconventional pollutants considered, 34 were not selected for regulation for the following reasons:

- Twenty-seven pollutants were discharged on an industry-wide basis at less than 3,000 lbs/yr. A review of their treatability, treatment performance data availability, number of facilities discharging, analytical methods, and load discharged does not support the need for regulation.
- Acetic acid and formic acid were excluded due to their low toxicity and because they will be treated by normal pH control measures as required by the pH range specified within the regulation.
- Glycol ethers were excluded due to the lack of an available analytical method. Methyl cellosolve, the predominant glycol ether reported as being used by the industry, has been selected for regulation at subcategory A/C facilities, where it is found.
- Dimethyl carbamyl chloride and Bis(chloromethyl)ether were excluded because they hydrolize in water and therefore do not persist in water.
- 2-methylpyridine was excluded because the pollutant is reported or detected in the effluent from one source and is uniquely related to this source.
- Trichlorofluoromethane was excluded because the pollutant was detected in the effluent from one source and is uniquely related to this source.

Table 6-4 lists these 34 nonconventional pollutants and the reasons for their exclusion from the list of pollutants to regulate. The remaining 39 were identified by the Agency as candidates for regulation:

Acetone
Acetonitrile
Ammonia
n-Amyl acetate
Amyl alcohol
Aniline
2-Butanone (MEK)
n-Butyl acetate
n-Butyl alcohol
tert-Butyl alcohol
COD (Chemical Oxygen Demand)
Diethylamine
N,N-Dimethylacetamide
N,N-Diemethylaniline
N,N-Dimethylformamide
Dimethyl sulfoxide
1,4-Dioxane
Ethanol
Ethyl acetate
Ethylene glycol
Formaldehyde
Formamide
n-Heptane
n-Hexane
Isobutyraldehyde
Isopropanol
Isopropyl acetate
Isopropyl ether
Methanol
Methyl cellosolve
Methyl formate
Methyl isobutyl ketone (MIBK)
Petroleum naphtha
Polyethylene glycol 600
n-Propanol
Pyridine
Tetrahydrofuran
Triethylamine
Xylenes

EPA analyzed the load reduction of these 39 nonconventional pollutants expected through implementation of BAT and PSES for A/C and B/D subcategories. 9 provides specific information on calculation of pollutant loads and pollutant load reduction. Table 6-5 presents the expected pollutant load reduction for the subcategories.

For A/C facilities, the following 15 nonconventional pollutants considered for regulation were found to have minimal load reduction (less than 178 lbs/year) and therefore have not been selected for regulation.

Aniline
2-Butanone (MEK)
n-Butyl alcohol
tert-Butyl alcohol
N,N-Dimethylacetamide
N,N-Diemethylaniline
N,N-Dimethylformamide
1,4-Dioxane
Ethylene glycol
Formaldehyde
Formamide
Petroleum naphtha
Polyethylene glycol 600
n-Propanol
Pyridine

The remaining 24 nonconventional pollutants have been selected for regulation at A/C facilities:

Acetone
Acetonitrile
Ammonia
n-Amyl acetate
Amyl alcohol
n-Butyl acetate
COD (Chemical Oxygen Demand)
Diethylamine
Dimethyl sulfoxide
Ethanol
Ethyl acetate
n-Heptane
n-Hexane
Isobutyraldehyde
Isopropanol
Isopropyl acetate
Isopropyl ether
Methanol
Methyl cellosolve
Methyl formate
Methyl isobutyl ketone (MIBK)
Tetrahydrofuran
Triethylamine
Xylenes

For B/D facilities, the following 34 nonconventional pollutants were found to have low load reduction (less than 323 lbs/year), and therefore have not been selected for regulation:

Acetone
Ammonia
Amyl alcohol
Aniline
2-Butanone (MEK)
n-Butyl acetate
n-Butyl alcohol
tert-Butyl alcohol
Diethylamine
N,N-Dimethylacetamide
N,N-Diemethylaniline
N,N-Dimethylformamide
Dimethyl sulfoxide
1,4-Dioxane
Ethanol
Ethylene glycol
Formaldehyde
Formamide
n-Heptane
n-Hexane
Isobutyraldehyde
Isopropanol
Isopropyl ether
Methanol
Methyl cellosolve
Methyl formate
Methyl isobutyl ketone (MIBK)
Petroleum naphtha
Polyethylene glycol 600
n-Propanol
Pyridine
Tetrahydrofuran
Triethylamine
Xylenes

The remaining five nonconventional pollutants have been selected for regulation for B/D facilities:

Acetone
n-Amyl acetate
Chemical Oxygen Demand (COD)
Ethyl acetate
Isopropyl acetate

Table 6-1

Pollutants Which May be Present in Pharmaceutical Industry Wastewater

Conventional Pollutants		**Nonconventional Pollutants**
BOD_5	Oil & Grease	Acetaldehyde
pH	Fecal Coliform	Acetic acid
TSS		Acetone
		Acetonitrile
Priority Pollutants		Acetophenone
		Allyl chloride
Acrolein		4-Aminobiphenyl
Acrylonitrile		Ammonia
Benzene		n-Amyl acetate
Benzidine		Amyl alcohol
Bromoform		Aniline
Bromomethane		Benzaldehyde
Chlorobenzene		Benzotrichloride
Chloroethane		Benzyl alcohol
Chloroform		Benzyl chloride
Chloromethane		Benzyl bromide
Cyanide		Biphenyl
1,1-Dichloroethane		Bis(chloromethyl)ether
1,2-Dichloroethane		2-Bromo-Propanoylbromide
1,1-Dichloroethene		2-Butanone (MEK)
1,2-Dichloropropane		n-Butyl acetate
Ethylbenzene		n-Butyl alcohol
Hexachlorocyclopentadiene		tert-Butyl alcohol
Hexachloroethane		sec-Butyl alcohol
Methylene chloride		n-Butylamine
Nitrobenzene		Carbon disulfide
2-Nitrophenol		Catechol
4-Nitrophenol		Chloroacetic acid
o-Dichlorobenzene		2-Chloroacetophenone
p-Dichlorobenzene		3-Chloro-4-Fluoroaniline
Phenol		Chloromethyl methyl ether
1,1,2,2-Tetrachloroethane		COD (Chemical Oxygen Demand)
Tetrachloromethane		
Toluene		Cresol (Mixed)
1,1,1-Trichloroethane		Cumene
Trichloroethylene		Cyclohexane
1,1,2-Trichloroethane		Cyclohexanone
Vinyl chloride		Cyclopentanone

Table 6-1 (Continued)

Nonconventional Pollutants (Continued)	
Cyclohexylamine	Iodomethane
1,2-Dibromoethane	Isobutyraldehyde
1,2-trans-Dichloroethene	Isopropyl ether
Diethylaniline	Isopropanol
Diethyl ether	Isopropyl acetate
Diethylamine	Isobutyl alcohol
Diethyl carbonate	Methanol
Diethyl-ortho formate	Methyl cellosolve
Dimethylamine	Methyl amine
1,1-Dimethylhydrazine	Methyl formate
N,N-Dimethylacetamide	2-Methyl pyridine
N,N-Dimethylformamide	2-Methoxyaniline
N,N-Dimethylaniline	Methyl methacrylate
Dimethylcarbamyl chloride	Methyl-t-butyl-ether
Dimethyl sulfoxide	Methylal
1,4-Dioxane	Methyl isobutyl ketone (MIBK)
N-Dipropylamine	N-Nitrosomorpholine
Epichlorohydrin	n-Octane
Ethanol	n-Pentane
Ethylene oxide	Petroleum naphtha
Ethylamine	Polethylene glycol 600
Ethyl bromide	1,3-Propane sulfone
Ethyl cellosolve	n-Propanol
Ethyl acetate	B-Propiolactone
Ethylene glycol	Propionaldehyde
Ethyl cyanide	1,2-Propyleneimine
Formaldehyde	Propylene oxide
Formamide	Pyridine
Formic acid	Styrene
Furfural	Tetrachloroethene
Glycol ethers	Tetrahydrofuran
n-Heptane	Trichlorofluoromethane
2-Hexanone	2,4,5-Trichlorophenol
n-Hexane	Triethylamine
Hydrazine	Vinyl acetate
Iodoethane	Xylenes

Table 6-2
Pollutant Selection Evaluation Criteria for Pollutants Discharged by the Pharmaceutical Manufacturing Industry

Constituent Code	Constituent Name	Constituent Type (a)	Quantity Discharged (lbs/yr) (b)	Percent of Total Loading	# of Facilities Reporting Constituents in Raw Load	# of Facilities Reporting Constituents Discharged
97	Methanol (Methyl Alcohol)	N	13,204,311	33.145	91	75
70	Ethanol	N	5,864,800	14.722	111	92
2	Acetic Acid	N	3,306,442	8.300	44	44
94	Isopropanol	N	3,071,721	7.711	102	85
118	Acetone	N	3,069,840	7.706	63	53
102	Methylene chloride	P	1,257,644	3.157	54	45
60	N,N-Dimethylacetamide	N	1,046,104	2.626	8	7
9	Ammonium hydroxide	N	927,804	2.329	54	30
81	Formic Acid	N	821,154	2.061	9	9
66	Dimethyl sulfoxide	N	750,576	1.884	15	14
27	N-Butyl alcohol	N	666,324	1.673	20	18
105	Methyl isobutyl ketone (MIBK)	N	638,193	1.602	9	9
101	Methyl cellosolve	N	445,137	1.117	4	4
3	Acetonitrile	N	430,191	1.080	18	15
136	Triethylamine	N	418,697	1.051	22	13
26	N-Butyl acetate	N	415,426	1.043	2	2
64	N,N-Dimethylformamide	N	387,298	0.972	27	21
79	Formaldehyde	N	313,190	0.786	29	24
71	Ethyl acetate	N	273,627	0.687	35	26
130	Toluene	P	265,859	0.667	49	41
129	Tetrahydrofuran	N	264,875	0.665	21	16
113	Petroleum naphtha	N	260,583	0.654	5	2
55	Diethylamine	N	218,020	0.547	10	7
124	Pyridine	N	212,039	0.532	14	10
11	Amyl alcohol	N	196,554	0.493	6	6

Table 6-2 (Continued)

Constituent Code	Constituent Name	Constituent Type (a)	Quantity Discharged (lbs/yr) (b)	Percent of Total Loading	# of Facilities Reporting Constituents in Raw Load	# of Facilities Reporting Constituents Discharged
37	Chloroform	P	181,517	0.456	16	14
77	Ethylene glycol	N	165,860	0.416	13	12
15	Benzene	P	120,200	0.302	2	1
10	n-Amyl acetate	N	113,485	0.285	5	5
29	Tert-Butyl alcohol	N	98,408	0.247	7	5
106	2-Methylpyridine	N	48,800	0.122	1	1
95	Isopropyl acetate	N	47,924	0.120	10	9
93	Isobutyraldehyde	N	35,654	0.089	3	2
115	Polyethylene glycol 600	N	31,219	0.078	8	8
84	N-Heptane	N	27,894	0.070	12	11
139	Xylenes	N	27,361	0.069	14	13
67	1,4-Dioxane	N	24,422	0.061	5	5
48	o-Dichlorobenzene	P	21,499	0.054	2	2
62	N,N-Dimethylaniline	N	18,155	0.046	3	2
25	2-Butanone (MEK)	N	17,426	0.044	6	4
83	Glycol ethers	N	14,483	0.036	6	6
103	Methyl formate	N	12,616	0.032	4	3
117	N-Propanol	N	11,439	0.029	6	4
96	Isopropyl ether	N	11,314	0.028	4	4
22	Bis(Chloromethyl)ether	N	11,221	0.028	1	1
114	Phenol	P	10,919	0.027	18	12
87	N-Hexane	N	10,796	0.027	17	8
80	Formamide	N	7,184	0.018	5	4
35	Chlorobenzene	P	5,606	0.014	5	4
51	1,2-Dichloroethane	P	4,612	0.012	8	6
12	Aniline	N	4,603	0.012	4	4
63	Dimethylcarbamyl chloride	N	3,973	0.010	1	1

Table 6-2 (Continued)

Constituent Code	Constituent Name	Constituent Type (a)	Quantity Discharged (lbs/yr) (b)	Percent of Total Loading	# of Facilities Reporting Constituents in Raw Load	# of Facilities Reporting Constituents Discharged
134	Trichlorofluoromethane	N	3,850	0.010	2	1
132	1,1,2-Trichloroethane	P	2,954	0.007	2	2
111	n-Octane	N	2,200	0.006	1	1
56	Diethylaniline	N	1,703	0.004	1	1
58	Diethyl ether	N	1,350	0.003	13	8
45	Cyclohexylamine	N	1,250	0.003	1	1
31	Carbon disulfide	N	1,100	0.003	1	1
14	Benzaldehyde	N	886	0.002	3	3
91	Iodomethane	N	845	0.002	2	2
33	Chloroacetic acid	N	800	0.002	2	2
61	Dimethylamine	N	756	0.002	4	1
123	Propylene oxide	N	742	0.002	1	1
44	Cyclohexanone	N	738	0.002	1	1
46	Cyclopentanone	N	678	0.002	1	1
100	Methyl-t-butyl-ether	N	588	0.001	2	2
43	Cyclohexane	N	491	0.001	10	4
72	Ethylamine	N	466	0.001	1	1
18	Benzyl alcohol	N	401	0.001	16	16
99	Methylamine	N	310	0.001	9	2
98	Methylal	N	252	0.001	1	1
39	Chloromethane	P	204	0.001	2	2
126	1,1,2,2-Tetrachloroethane	P	120	0	1	1
78	Ethylene oxide	N	105	0	3	3
131	1,1,1-Trichloroethane	P	91	0	4	4
73	Ethylbenzene	P	90	0	1	1
92	Isobutyl alcohol	N	46	0	1	1
1	Acetaldehyde	N	33	0	1	1

Table 6-2 (Continued)

Constituent Code	Constituent Name	Constituent Type (a)	Quantity Discharged (lbs/yr) (b)	Percent of Total Loading	# of Facilities Reporting Constituents in Raw Load	# of Facilities Reporting Constituents Discharged
89	Hydrazine	N	17	0	2	2
75	Ethyl cellosolve	N	5	0	1	1
20	Benzyl Chloride	N	5	0	2	2
7	Allyl chloride	N	5	0	1	1
74	Ethyl bromide	N	5	0	2	2
82	Furfural	N	4	0	3	1
128	Tetrachloromethane	P	1	0	1	1

(a) N-Nonconventional Pollutant
P-Priority Pollutant
(b) Quantity discharged is equal to the discharge to surface water and/or sewer (1lbs) from Table 3-2 of the Detailed Questionnaire.

Table 6-3

Priority Pollutants Not Selected for Regulation in the Pharmaceutical Manufacturing Industry

Pollutant	Reason for Exclusion
Tetrachloromethane	Discharged in trace amounts from one facility (1 lb/yr)
Ethylbenzene	Discharged in trace amounts from one facility (90 lbs/yr), low toxicity
1,1,1-Trichloroethane	Discharged in trace amounts (91 lbs/yr), low toxicity
1,1,2,2-Tetrachloroethane	Discharged in low amounts from one facility (120 lbs/yr)
Chloromethane	Discharged in low amounts from two facilities (204 lbs/yr)
1,1,2-Trichloroethane	Discharged in low amounts from two facilities (2,954 lbs/yr)

Table 6-4

Nonconventional Pollutants Not Selected for Regulation in the Pharmaceutical Manufacturing Industry

Pollutant	Reason for Exclusion
Allyl chloride	Discharged in trace amounts from one facility (5 lbs/yr), low toxicity
n-Octane	Discharged in low amounts from one facility (2,200 lbs/yr), low toxicity
Diethylaniline	Discharged in low amounts from one facility (1,703 lbs/yr), low toxicity
Cyclohexylamine	Discharged in low amounts from one facility (1,250 lbs/yr), low toxicity
Carbon disulfide	Discharged in low amounts from one facility (1,100 lbs/yr), low toxicity
Propylene oxide	Discharged in low amounts from one facility (742 lbs/yr)
Iodomethane	Discharged in low amounts from two facilities (845 lbs/yr), low toxicity
Chloroacetic acid	Discharged in low amounts from two facilities (800 lbs/yr), low toxicity
Cyclohexanone	Discharged in low amounts from one facility (738 lbs/yr), low toxicity
Cyclopentanone	Discharged in low amounts from one facility (678 lbs/yr), low toxicity
Methyl-t-butyl-ether	Discharged in low amounts from two facilities (588 lbs/yr), low toxicity
Methylal	Discharged in low amounts from one facility (252 lbs/yr), low toxicity
Ethylamine	Discharged in low amounts from one facility (466 lbs/yr), low toxicity
Ethyl bromide	Discharged in trace amounts from two facilities (5 lbs/yr), low toxicity
Ethyl cellosolve	Discharged in trace amounts from one facility (5 lbs/yr)
Benzyl chloride	Discharged in trace amounts from two facilities (5 lbs/yr)
Isobutyl alcohol	Discharged in trace amounts from one facility (46 lbs/yr), low toxicity
Hydrazine	Discharged in trace amounts from two facilities (17 lbs/yr)
Acetaldehyde	Discharged in trace amounts from one facility (33 lbs/yr)
Acetic acid	Addressed by pH control under BPT
Formic acid	Addressed by pH control under BPT
Benzaldehyde	Discharged in low amounts (886 lbs/yr), low toxicity
Benzyl alcohol	Discharged in low amounts (401 lbs/yr), low toxicity
Ethylene oxide	Discharged in low amounts (105 lbs/yr)
Glycol ethers	No analytical method available
Dimethyl carbamyl chloride	Hydrolysis/does not persist in water
Bis(chloromethyl)ether	Hydrolysis/does not persist in water
Diethyl ether	Discharged in low amounts from eight facilities (1,350 lbs/yr)
Cyclohexane	Discharge in low amounts from four facilities (491 lbs/yr)
Dimethylamine	Discharged in low amounts from one facility (756 lbs/yr)

Table 6-4 (Continued)

Pollutant	Reason for Exclusion
Methylamine	Discharged in low amounts from two facilities (310 lbs/yr)
Furfural	Discharged in trace amounts from one facility (4 lbs/yr)
2-Methylpyridine	Discharged from one facility (48,800 lbs/yr), unique to one facility
Trichlorofluoromethane	Discharged in low amounts from one facility (13,850 lbs/yr), unique to one facility

REFERENCES

1. Natural Resources Defense Council, Inc, et al., v. Russel E. Train, 8 ERC 2120 (D.D.C. 1976) modified and Natural Resources Defense Council, Inc., et al., v. Douglas M. Costle, 12 ERC 1833 (D.D.C. 1979).

2. U.S. EPA, Office of Water Regulations and Standards. Preliminary Data Summary for the Pharmaceutical Manufacturing Point Source Category, EPA 440/1-89/084, U.S. Environmental Protection Agency, Washington, D.C. September 1989.